HOVERTECH International

K121287

"510(k) SUMMARY" as required by section 807.92(c)

OCT 3 2012

Submitter Information:

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T/A HoverTech International
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Contact Person:

Susan Pavelko
Quality Manager
D. T. Davis Enterprises, LTD

Date Summary Prepared: April 24, 2012

Trade Name: HT-Wedge

Common Name: Lift, Patient, AC Powered

Classification Name: AC-powered patient lift (21 CFR 880.5500, Product Code FNG)

Legally Marketed Device: HoverTech International HoverJack Air Patient Lift
510(k)#: K041503

Device Description: The HT-Wedge is an inflatable wedge with square headrest and two intake appendages, one for the head and one for the chest. An inflation/deflation valve is found in each appendage. There is also a tongue attached to the wedge that lies under the patient's buttocks. The inflatable portion of the product is 22" wide and 31 ¼" long. There are four attachment straps, two located on each side of the wedge in order for it to be secured to the OR table. The tongue adds an additional 20" in length. The wedge is constructed of polyurethane coated nylon with 2 one-way, inflation/deflation valves.

The HT-Wedge is similar in use and function to the HoverJack Air Patient Lift, registered by D. T. Davis Enterprises, LTD., which is a Class II Device with Product Code FNG.

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Indications for Use: The purpose of the HT-Wedge is to pneumatically lift and position the head and chest of a patient who is lying in the supine position without manual lifting.

Device Comparison: The HoverTech International® HT-Wedge is substantially equivalent to the HoverJack air patient lift, registered by D. T. Davis Enterprises, LTD. in function and intended use. The differences described in the submission between the HoverTech International® HT-Wedge and that of the predicate devices do not raise any new issues of safety or effectiveness. The intended use for each system is the same. The basic technology is exact since they both require the same UL Listed air supply and make use of the same one-way inflation/deflation valve. The power source is only attached to device during inflation, once the device has reached it desired firmness the air supply is removed and the one-way valve is in a closed position. The basic technology and performance characteristics of these systems are the same.

The subject device is intended to be used in any clinical environment where patient care is administered. Health facilities ordinarily used AC powered lifts to place patients in the proper position for ancillary procedures, while reducing the risk of injury to the caregiver and patient.

The labels and labeling (Information Sheet) provide information for the safe operation by the caregiver/user and the intended operation features.

No performance standards or special controls have been promulgated for patient positioning supports under sections 513 and 514 of the FD&C Act.

Safety Testing and performance characteristics have been conducted and successfully completed in order to ensure compliance with specifications. These reports are maintained as required by 21 CFR 820, Quality Systems Regulations.

An assessment of known and reasonable hazards has been conducted to ensure that any risk associated with the device as of the date of product release is as low as reasonably possible. Design review has been conducted by a cross-functional team, including but not limited to regulatory, quality, engineering and manufacturing.

The device will comply with the following voluntary standards:

- ISO 10993-5ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices-- Part 10: Tests for Irritation and Sensitization
- ISO 10993-1:2009/Cor1:2010(E) Biological evaluation of medical devices – Part 1 Evaluation & testing within a risk management process

Conclusion:
The HT-Wedge and its predicate device included in this submission are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 3 2012

D.T. Davis Enterprises, Limited
T/A HoverTech International
Ms. Susan Pavelko
Quality Manager
513 South Clewell Street
Bethlehem, Pennsylvania 18015

Re: K121287
Trade/Device Name: HT-Wedge
Regulation Number: 21 CFR 880.5500
Regulation Name: AC-Powered Patient Lift
Regulatory Class: II
Product Code: FNG
Dated: September 14, 2012
Received: September 21, 2012

Dear Ms. Pavelko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121287

Device Name: HT-Wedge

Indications For Use:

The purpose of the HT-Wedge is to pneumatically lift and position the head and chest of a patient who is lying in the supine position without manual lifting.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Richard C Chapman

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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